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09/865,196	05/24/2001	Kok-Hwee Ng	F4-5728 (1417P P 591)	2014

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Bradford R.L. Price, Esq.  
Senior Counsel  
Baxter International Inc.  
Route 120 and Wilson Road, RLP-30  
Round Lake, IL 60073

EXAMINER

SHAPIRO, JEFFERY A

ART UNIT	PAPER NUMBER
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3653

DATE MAILED: 12/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/865,196

Applicant(s)

NG ET AL.

Examiner

Jeffrey A. Shapiro

Art Unit

3653

*MS*

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 58-90 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 58-90 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The information disclosure statement filed 11/8/04 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.
2. The MPEP states at 609 (A3): Although a concise explanation of the relevance of the information is not required for English language information, Applicant is encouraged to provide a concise explanation of why the English language information is being submitted and how it is understood to be relevant. Concise explanations (especially those which point out the relevant pages and lines) are helpful to the Office, particularly where documents are lengthy and complex and Applicant is aware of a section that is highly relevant to patentability or where a large number of documents are submitted and Applicant is aware that one or more are highly relevant to patentability.

In the instant application no such explanations have been offered.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3653

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 58-90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Langley (US 233,525 B1) in view of Engleson et al (US 5,781,442) and further in view of Brown (US 6,451,203 B2) and still further in view of Baluyot. Langley discloses a system for monitoring and tracking at least a portion of a blood component collection procedure in a blood component facility, performed upon a donor by an operator, as follows.

As described in Claim 58;

- a. a blood component collection instrument (18 and needle assembly, see col. 5, lines 28-30) for collecting a blood component from a donor;
- b. the donor having a donor identifier (see col. 9, lines 22-41) and the blood component collection instrument having a blood collection instrument identifier (note that it would be expedient for one ordinarily skilled in the art to provide such an identifier—see Baluyot et al, figure 1 and col. 3, lines 34-41);
- c. a blood component collection kit having a blood component collection kit identifier, the blood component collection kit for collecting the blood component from the donor; (Note that the blood collection kit includes a bag/container to store the blood in, which would be obvious to identify by one ordinarily skilled in the art with a particular patient/donor since the blood must be tracked from the donor to the patient to secure

against problems with the blood based on the donor's health condition.

See also Engleson et al which tracks consumables (140) (see col. 10, lines 55-67 of Engleson et al) and uses bar codes to identify a number of system variables, as shown in figures 4, 5, 5A and 6. *Note that blood components are construed as consumables as such blood products, for example, plasma, are routinely required for surgeries, etc. Note also col. 1, lines 47-51, which describes a blood sample being identified as being from a particular patient.)*

d. a central input station (computer (148), see col. 4, lines 44-50) being operably connected to the blood component collection instrument (see col. 4, lines 50-65), the central input station comprising a program having a plurality of code segments, at least one code segment monitoring operation of a blood component collection instrument *during operation of the blood component collection instrument;*

(See figure 5, noting "perform collection procedure" and "data transfer back to central station"—note also that the central input station can be considered to be a server, or at the very least, part of a network, as suggested by col. 13, lines 25-30—see also figure 5, noting *"transfer/download collection device controller" step.*)

e. a memory operably connected to the system server, the memory for storing information received by the central input station (note that computers must have memory in order to store information—*note also that*

*disk (142) of Langley stores information and is a form of memory—see also Engleson, col. 7, lines 41-43, which mentions storage of data in a CPU memory or on a disk);*

f. an interface operably connected to the system server, the interface having a display for monitoring the at least one portion of the blood component collection procedure (see figure 1, noting the computer (148) with display, keyboard and mouse);

As described in Claims 59 and 82;

g. a report comprising information from the memory, the information in the memory being selected from the group consisting of data blood component collection instrument data, operator data and donor data (note that Langley, col. 9, lines 42-61, for example, describe output which include such data, noting also that it would be expedient for one ordinarily skilled in the art to organize such data into an output such as a printed report);

As described in Claims 60 and 82;

h. the interface comprises a reader for entering information to be transmitted to the system server and received by the program for monitoring the blood collection kit, the blood component collection kit identifier being transmitted to the system server via the reader;

As described in Claim 61;

- i. a blood component collection process number is associated with the blood component collection procedure, the donor, the blood collection kit and the blood collection instrument, wherein the interface transmits the donor identifier, the collection kit identifier and the blood component collection instrument identifier to the system server (See also Engleson et al which tracks consumables (140) and uses bar codes to identify a number of system variables, as shown in figures 4, 5, 5A and 6);

As described in Claim 62;

- j. the interface is remotely located from the blood component collection instrument (note that the computer (148) is located at a point away from the blood collection instrument as shown in figure 1);

As described in Claim 63;

- k. a blood component collection process number is associated with the blood component, and wherein the blood component collection instrument identifier, the blood donor identifier and the blood component collection process number are associated with the blood collection kit (See also Engleson et al which tracks consumables (140) and uses bar codes to identify a number of system variables, as shown in figures 4, 5, 5A and 6);

As described in Claim 64;

- l. a label is created in response to a change of status of the blood component collection kit (see Beecham, US 5,897,989) which uses label

device (24), noting that it would be expedient for one ordinarily skilled in the art to provide a label);

As described in Claim 65;

m. a blood collection kit inventory database, the blood collection kit inventory database operably connected to a blood collection kit supply wherein the blood collection kits can be replenished at the blood collection facility as needed (see Eagleson, col. 3, lines 12-20, which describes use of an inventory database as part of a system for collecting patient data and managing patient care);

As described in Claim 66;

n. the program automatically updates the blood collection kit inventory database in response to the blood collection kit identifier being input into the interface (note that it would be obvious to one ordinarily skilled in the art to update the inventory database based upon removal or inclusion of blood collection kits, or other consumables such as needles, drugs, alcohol, swabs and bandages, for example);

As described in Claim 67;

o. a remote server operably connected to the system server via a communication network, the remote server monitoring and tracking a remote blood collection facility (note that Engleson et al also teaches use of a server based system, which one ordinarily skilled in the art would



recognize as easily adaptable to be used with the system of Langley, so as to provide a full range of patient data information);

As described in Claim 68;

p. the interface comprises a screen menu for providing information about the blood collection kit (see Engleson, figures 7-12, noting that it would be expedient for one ordinarily skilled in the art to provide such data as part of the healthcare data information screens described and illustrated);

As described in Claims 69 and 82;

q. the interface comprises;

- i. a reader (see Engleson, figure 2, element (69)) for entering information;
- ii. a transmitter for transmitting information to the server (note that the bar code reader and printer are connected by wire to the pharmacy CPU (60));

As described in Claims 70 and 82;

r. a receiver (See Engleson (40)) for receiving information from the server;

s. a web browser cooperating with the server, the web browser for displaying information saved in the memory; (See Engleson, noting that the web browser is shown in figures 7-12 and

As described in Claim 70;

- t. the interface utilizes radio frequency (see Engleson, col. 3, lines 21-24) to transmit to the system server;

As described in Claim 71;

- u. the reader comprises a touch pad (see Engleson, figure 2, element (73) for entering information into the program;

As described in Claim 72;

- v. the reader comprises a touch pad for entering information into the program (note that a touch pad is a functional equivalent of a touch screen);

As described in Claim 73;

- w. the interface comprises a stylus for cooperating with the touch pad wherein written text can be entered (note that a stylus is a functional equivalent of a touch screen);

As described in Claim 74;

- x. the reader comprises a keypad for entering information into the program (see either Engleson or Langley);

As described in Claim 75;

- y. the reader comprises an optical scanner for entering information into the program (note that bar code reader of Engleson (69) is such a scanner);

As described in Claim 76;

z. the reader comprises a magnetic scanner for entering information into the program (note that this is a functional equivalent of a bar code reader);

As described in Claim 77;

aa. the interface comprises a menu for monitoring the at least one portion of the blood component collection procedure (see Engleson menus, figures 7-12, noting that it would be expedient to provide such capabilities in the menus of Engleson);

As described in Claim 78, 89 and 90;

ab. the interface comprises a menu for tracking the at least one portion of the blood component collection procedure;  
(See Engleson menus, figures 7-12, noting that it would be expedient to provide such capabilities in the menus of Engleson); (Note also that Baluyot teaches the use of barcode identifiers for linking the sample containers, the collection instrument, and the bleed number.)

As described in Claim 79;

ac. a communication conduit operably connecting the blood component collection instrument to the system server (note that a wire is a communication conduit, which both Langley and Engleson et al use throughout their systems); and  
ad. a web interface being operably connected to the system server, the web interface providing access to the system server for monitoring the at

least one portion of the blood component collection procedure (see Engleson menus, figures 7-12, noting that it would be expedient to provide such capabilities in the menus of Engleson);

As described in Claim 80;

ae. the communication conduit utilizes Ethernet (see col 4, line 37 of Engleson);

As described in Claim 81;

af. wherein the communication conduit utilizes TCP/IP (note that it would be expedient for one ordinarily skilled in the art to use such a protocol, especially, for a network which would use the internet);

As described in Claim 83;

ag. a fifth segment of the computer readable medium for determining eligibility of the donor (note that it is well known that blood screening is used by the red cross to screen for items such as hepatitis or HIV—see Quattrocchi (US 5,978,466) which describes a method for testing for HIV, as well as another system which tracks a blood component sample, kit and donor/patient);

As described in Claim 84;

ah. a sixth segment for generating a bleed number (see Baluyot et al, lines 6-40);

ai. a seventh segment for linking the blood component collection instrument to the bleed number (see also Engleson et al which tracks

consumables (140) and uses bar codes to identify a number of system variables, as shown in figures 4, 5, 5A and 6.), noting that it would be expedient to identify and link any number of variables and items required in such a procedure as taking blood);

aj. an eighth segment for linking the donor to the bleed number;

As described in Claim 85;

ak. a ninth segment for monitoring the at least a portion of the blood component collection procedure by utilizing the information received from the blood component collection instrument (see previous);

As described in Claim 86;

al. a tenth segment for reading a blood component collection kit identifier associated with a blood component collection kit;

am. an eleventh segment for storing the blood component collection kit identifier in the system server; and

an. a twelfth segment for linking the blood component collection kit with the bleed number;

(note again that Engleson et al provides a bar code reader and bar code labels, which one ordinarily skilled in the art would find expedient to place on any part of the system required to identify it to said system)

As described in Claim 87;

ao. a thirteenth segment for generating a report utilizing the information received from the blood component collection instrument (note again that

report generation would have been expedient to one ordinarily skilled in the art);

As described in Claim 88;

ap. a fourteenth segment for generating a report in utilizing the information received from the interface (note again that report generation would have been expedient to one ordinarily skilled in the art);

Langley does not expressly disclose but Brown discloses the following.

As described in Claims 58 and 82;

the central input station comprising a program having a plurality of code segments, at least one code segment monitoring operation of a blood component collection instrument *during operation of the blood component collection instrument*; (See Brown, figure 2, noting that application control manager (46) controls and monitors various blood drawing and processing procedures. See also Brown, col. 6, lines 22-67, col. 7, lines 1-67, and Col. 8, lines 1-51.)

Langley, Engleson, Baluyot and Brown are considered to be analogous art because Engleson describes a patient information collection, tracking and monitoring system, Langley describes a blood component collection device which compiles information about the blood component collection process and Brown describes a blood

collection and processing system with operational monitoring of the drawing process. Note that Baluyot describes using a barcode to link various blood containers.

At the time of the invention, it would have been obvious to use the system of Langley with the systems of Engleson and Brown, integrating them so as to work in concert with each other. Baluyot et al teaches the use of barcode identifiers for linking the sample containers, the collection instrument, and the bleed number, again, as described above.

The suggestion/motivation for combining Langley and Engleson's systems would have been to input information about the blood collection process to a complete patient data collection and management system. This would better provide a way to control healthcare costs, among other things as well as to provide more complete data for bio-emergencies such as disease outbreaks which might affect the blood supply as well as blood usage problems which might strain the blood component supply system.

The suggestion/motivation to combine the systems of Langley and Brown is that Langley discloses a blood component collection system with optimizer. Brown also discloses a blood component collection system with real time process monitoring with an optimizer. It would have been obvious to use the blood process monitoring portion of Brown with the system of Langley because Langley's system collects blood and would require process monitoring to enable the optimizer of Langley to perform its function.

The suggestion/motivation for using Baluyot's teaching regarding barcodes linking containers and bleed numbers is that Langley is a blood component collection

system and would require linking containers with blood from specific patients with their bleed numbers, a particular characteristic of the patient's blood donation process.

Therefore, it would have been obvious to combine Engleson, Brown, Baluyot and Langley in order to obtain the system described in Claims 58-90.

### ***Response to Arguments***

5. Applicant's arguments filed 11/8/04 have been fully considered but they are not persuasive. Applicant asserts that Langley does not teach "monitoring" the blood drawing process "during operation of the blood drawing equipment." However, this is not true. Applicant refers to Langley at col. 14, lines 12-15 as stating that the "data is transferred back to the central station only after the collection procedure is completed." Applicant's Remarks, p. 4, lines 27-29. Applicant also refers to Langley col. 13, lines 16-31 in this regard. See Remarks, p. 3, lines 15-26.

However, this information has been generated during the blood drawing process. See Langley, col. 13, lines 40-44, which states that "this optimization process may be utilized before the collection procedure is actually initiated, but may also be initiated **during** a given collection procedure..." Emphasis provided.

Additionally, "monitoring" is a broad term that can be interpreted to encompass human interpretation of data in conjunction with the machine.

Also, one ordinarily skilled in the art would recognize that the data, as referred to in the previous cites, is monitored and collected during the process and then transferred/downloaded after the monitoring process. Otherwise, there would be no data to download.



***Conclusion***

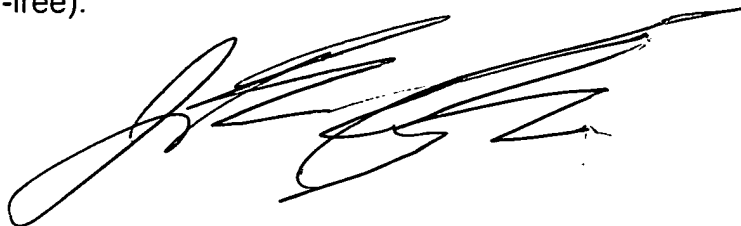
**6. THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

**7.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey A. Shapiro whose telephone number is (703)308-3423. The examiner can normally be reached on Monday-Friday, 9:00 AM-5:00 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Donald P. Walsh can be reached on (703)306-4173. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jeffrey A. Shapiro  
Examiner  
Art Unit 3653

December 15, 2004



RONALD D. WALS  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3600